RL/REG-2000-11
Revision 0

REGULATORY UNIT SELF-ASSESSMENT

May 5, 2000

Office of Safety Regulation of the TWRS-P Contractor

U.S. Department of Energy
Richland Operations Office
P.O. Box 550, A4-70
Richland, Washington 99352

RL/REG-2000-11
Revision 0

REGULATORY UNIT SELF-ASSESSMENT

May 5, 2000

Office of Safety Regulation of the TWRS-P Contractor

U.S. Department of Energy
Richland Operations Office
P.O. Box 550, A4-70
Richland, Washington 99352

Approved by: _____
Regulatory Official

Date: _____

PREFACE

The U.S. Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal in February 1996 for privatized processing of waste as part of the Hanford Tank Waste Remediation System (TWRS) program which in 1999 came under the cognizance of the Office of River Protection (ORP). Offerors were requested to submit proposals for the initial processing of the tank waste at the Hanford Site. Some of this radioactive waste has been stored in large underground storage tanks at the Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 250,000 metric tons of processed chemicals and 215 million curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE intends to purchase waste processing services from a Contractor-owned, Contractor-operated facility through a fixed-price contract. DOE will provide the waste feedstock for processing but maintain ownership of the waste. The Contractor must: (a) provide private financing; (b) design the equipment and facility; (c) apply for and receive required permits and licenses; (d) construct the facility and commission its operation; (e) operate the facility to process tank waste according to DOE specifications; and (f) deactivate the facility.

The TWRS Privatization (TWRS-P) project is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort. The objectives of Phase I are to (a) demonstrate the technical and business viability of using privatized Contractors to process Hanford tank waste; (b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; (c) maintain environmental protection and compliance; and (d) substantially reduce life-cycle costs and time required to process the tank waste. The Phase I effort consists of three parts: Part A, Part B-1, and Part B-2.

Part A, which concluded in August 1998, was a 20-month period to establish technical, operational, regulatory, and financial elements necessary for privatized waste processing services at fixed-unit prices. This included identification by the TWRS-P Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the 20-month period, 16 months was for the Contractors to develop the Part A deliverables and four months was for DOE to evaluate the deliverables and determine whether to authorize Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B-1.

Part B-1 is a 24-month period to (a) further the waste processing system design introduced in Part A, (b) revise the technical, operational, regulatory, and financial elements established in Part A, (c) provide firm fixed-unit prices for the waste processing services, and (d) achieve financial closure.

Part B-2 is a 16-year period to complete design, construction, and permitting of the privatized facilities; provide waste processing services for representative tank wastes at firm fixed-unit prices; and deactivate the facilities. During Part B-2, approximately 10% by volume (25% by activity) of the total Hanford tank wastes will be processed.

Phase II will be a full-scale production effort. The objectives of Phase II are to implement the lessons learned from Phase I and to process all remaining tank waste into forms suitable for final disposal.

An essential element of the TWRS-P Project is DOE's approach to safety regulation. DOE has specifically defined a regulatory approach and chartered a dedicated Office of Safety Regulation of the TWRS-P Contractor (Regulatory Unit). The DOE aim in proceeding with the safety regulation of the TWRS-P Contractor is to establish a regulatory environment that will permit privatization to occur on a timely, predictable, and stable basis. In addition, attention to safety must be consistent with that which would accrue from regulation by external agencies. DOE is patterning its radiological and nuclear safety regulation of the TWRS-P Contractor to be consistent with that of the U.S. Nuclear Regulatory Commission (NRC). For industrial hygiene and safety (IH&S), regulation is consistent with that of the Occupational Safety and Health Administration (OSHA).

The RL Manager has responsibility and authority for safety regulation and has assigned this authority to the RL Director of the TWRS-P Regulatory Unit (the Regulatory Official). This regulatory authority is exclusive to the regulation of the TWRS-P Contractor. The Regulatory Official is the formal point of execution for safety regulation of the TWRS-P Contractor.

The DOE requires the Contractor to integrate safety into work planning and execution. This Integrated Safety Management (ISM) process emphasizes that it is the Contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. The privatized Contractor has primary responsibility for safety. The DOE, through its program, is responsible for verifying that the Contractor establishes and complies with approved safety limits.

The relationship between DOE and the privatized Contractor performing work under a fixed-price contract is different than the relationship under traditional Management and Operations (M&O) contracts. For fixed-price contracting to be successful, this different safety relationship with the Contractor is accompanied by modified relationships among DOE's internal organizations. For example, the arrangement by which the RL Manager applies regulation to the TWRS-P Contractor should be a surrogate for an external regulator (such as the NRC or OSHA) with strong emphasis on independence, reliability, and openness.

Regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

All documents issued by the Office of Safety Regulation of the TWRS-P Contractor are available to the public through the DOE/RL Public Reading Room at the Consolidated Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.

RECORD OF REVISION

Document Title: Regulatory Unit Self-Assessment

Document Number: RL/REG-2000-11

Revision Date	Revision Number	Reason for Revision
5/05/00	0	New Issue.

This page left intentionally blank.

EXECUTIVE SUMMARY

From March 20 - April 7, 2000, the Regulatory Unit (RU) performed a self-assessment to determine if management systems and processes were in place to accomplish its assigned regulatory functions. The RU was assessed against specific criteria in the following ten areas:

- Management and organization – The organization was structured and staffed in a manner to complete its tasks.
- Interfaces – The functional interfaces were established, understood, and implemented.
- Staffing – The staffing size and experience supported completion of the expected tasks.
- Technical standards and requirements – The regulations, safety principles, and criteria that ensure the health and safety of the workers, public, and environment were in place and being implemented.
- Authorization process – An authorization process was established and implemented.
- Document reviews – Document reviews were comprehensive, accurate, timely, and consistent.
- Inspection and enforcement – An inspection program was in place and implemented.
- Lessons learned and corrective action – The organization was effectively using lessons learned and implementing the necessary corrective actions.
- Integrated safety management – An integrated safety management program was being implemented.
- Quality assurance – The RU was following the Quality Assurance Plan of the U.S. Department of Energy's Richland Operations Office (RL).

The self-assessment team (team) reviewed documents related to Tank Waste Remediation System Privatization Project and interviewed personnel from the RU and its support contractors, DOE/RL, DOE's Office of River Protection, DOE-Headquarters, the U.S. Nuclear Regulatory Commission, and BNFL Inc. Comparing the information derived from the document reviews and interviews to the evaluation criteria, the team developed observations, conclusions, and recommendations.

In general, the team concluded that the RU management systems and processes were in place to accomplish the RU's responsibilities and that the RU was effectively managing the regulatory program. In particular, the RU was accomplishing its regulatory responsibilities as outlined in RL/REG-97-10, *Regulatory Plan*, which defines implementation of the Policy[1] and the

[1] DOE/RL-96-25, *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1996.

Memorandum of Agreement.[2] The RU was structured and staffed to complete its tasks; the functional interfaces were established, understood, and implemented; and the RU's staffing size and experience supported completion of its assigned tasks. In addition, the team determined that the RU had established and implemented an authorization process and the regulatory framework for ensuring that the health and safety of the workers, public, and environment were protected. The RU had established an effective document review process to ensure that documents from BNFL received a timely and thorough review and had implemented a comprehensive inspection program for the current stage of the project. The team also concluded that while the RU had a lessons-learned process in place, the process could be expanded beyond its current use. In addition, implementation of an integrated safety management program within the RU could be strengthened. Finally, the team found that while elements of the RL quality assurance program were found throughout the RU, the RU should document more formally how it will meet the requirements of RL's quality assurance program.

As part of the self-assessment, the personnel interviewed were asked for suggestions on how the RU could be improved. Over 60 suggestions were received from the interviewees. These suggestions were compiled, combined, and screened, as appropriate, and are presented in this report as suggested areas for improvement. It should be recognized that the suggestions offered were for a program that overall was working well and thus were offered in the spirit of making the RU even more effective. In all, 20 recommendations for improvement are summarized in this report.

[2] DOE/RL-96-26, *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1996.

Table of Contents

Appendixes

Tables

REGULATORY UNIT SELF-ASSESSMENT REPORT

1.0 INTRODUCTION

In February 1998, the Office of Safety Regulation of the Tank Waste Remediation System Privatization (TWRS-P) Contractor (Regulatory Unit) performed a self-assessment of its management and quality assurance processes. The self-assessment identified a number of process weaknesses and developed 13 recommendations for the Regulatory Unit (RU) to consider. Many of the recommendations simply reinforced actions that the RU already had underway.

RU self-assessments were required to be conducted whenever the project undergoes significant transitions or at intervals not to exceed two years (RL/REG-97-10, *Regulatory Plan*). The elements of the self-assessment are described in RL/REG-97-10.

1.1 Purpose and Scope

In March 2000, the RU Regulatory Official (RO) requested that another self-assessment be conducted to assess the RU's progress and compliance with RU top-level documents and management directives (MDs) and to identify areas where the processes being applied could be improved. The self-assessment was also to verify that the management systems described in the applicable requirements were in place and functional and that the RU was positioned for success in the next phase of the project. Where shortcomings were identified, recommendations for improvement were generated.

The self-assessment evaluated the following ten areas:

- Management and organization – The organization was structured and staffed in a manner to complete its tasks.
- Interfaces – The functional interfaces were established, understood, and implemented.
- Staffing – The staffing size and experience supported completion of the expected tasks.
- Technical standards and requirements – The regulations, safety principles, and criteria that ensure the health and safety of the workers, public, and environment were in place and implemented.
- Authorization process – An authorization process was established and implemented.
- Document reviews – Document reviews were comprehensive, accurate, timely, and consistent.
- Inspection and enforcement – An inspection program was in place and implemented.

- Lessons learned and corrective actions – The organization was effectively using lessons learned and implementing the necessary corrective actions.

- Integrated safety management (ISM) – An ISM program was implemented.

- Quality assurance – The RU was following the Quality Assurance Plan of the U.S. Department of Energy's Richland Operations Office (RL).

These subject areas and the top-level criteria for assessing these areas are listed in Appendix A. The self-assessment team also reviewed progress made since the last self-assessment (February 1998), including RU status in carrying out the 13 recommendations from that self-assessment. That assessment is discussed in Section 2.11.

1.2 Self-Assessment Approach

The self-assessment was completed using a combination of interviews of RU and outside personnel and a review of RU documents.

The self-assessment team interviewed cognizant RU individuals and its support contractors as well as individuals from RL, DOE Headquarters (HQ) (by phone), the U.S. Nuclear Regulatory Commission (NRC), the Office of River Protection (ORP), and BNFL Inc. (BNFL). Individuals were interviewed in one to four self-assessment subject areas related to their assigned work, using a preselected standard set of questions. The self-assessment team discussed each interview after it was completed to develop conclusions and possible recommendations. Appendix B lists the personnel interviewed.

From each individual, the interviews solicited information, opinions, and conclusions from their experience in executing the regulatory mission. Information obtained during the interviews was evaluated and used, as appropriate, to generate this final assessment report. The interviews also sought to identify specific suggestions for improvement. Suggested improvements were discussed by the self-assessment team, combined as appropriate, screened, and then reworked into recommendations for improvement. It should be recognized that the suggestions for improvement were offered for a program that overall was working well and thus were offered in the spirit of making the RU even more effective.

The self-assessment team also reviewed various RU documents to determine if any work areas were not being done and to determine if the regulatory documents and MDs were being followed. (See Appendix C for a listing of the RU documents reviewed). The team compared actual RU activities against the processes described in RU MDs and other RU top-level documents. The self-assessment team also reviewed documents that the RU had issued to verify that they were clear, useful, and timely. The self-assessment team also used reports from previous internal and external assessments as background information and as a source for potential lines of inquiry.

Finally, the self-assessment team observed "work-in-progress" by attending selected meetings, such as the RU/ORP biweekly meeting, the RU weekly Work Plan and staff meetings, and an RU/BNFL topical meeting.

At the start of the self-assessment, the team held an entrance meeting with the RO and his staff. At the completion of the field work, the team conducted an exit briefing with the RO to outline the preliminary conclusions of the self-assessment. A draft report of the team assessment was submitted to the RO for review and comment before this final report was completed.

1.3 Self-Assessment Team

The self-assessment team included the following individuals:

- Patrick Carier – Lead: RU Verification and Confirmation Official
- Chung-King Liu – Senior RU Technical Advisor
- Ronald Lerch – Member of RU Senior Technical Team.

2.0 RESULTS AND CONCLUSION

The evaluation criteria and subcriteria, observations, conclusions, and recommendations from the self-assessment are summarized below for each of the ten areas evaluated. (See Appendix D for a summary of the self-assessment's recommendations presented for RU consideration.)

2.1 Management and Organization

2.1.1 Evaluation Criteria

The primary criteria for evaluating management and organization were as follows:

- The RU organization was structured and staffed in a manner to complete its tasks within schedule, while ensuring safety.
- The RU's authorities and responsibilities were clearly understood and discharged.
- The RU's organizational practices provided a sound safety culture.

Subcriteria for evaluating management and organization were as follows:

- The RU's structure ensured that it functioned effectively and efficiently.
- The RU's organization focused resources and provided clear lines of control and coordination.
- The RU had the authority needed to ensure it performed its responsibilities.
- The RU performed, or had functional interfaces to support, essential regulatory functions.
- The RU was independent of the regulated organizations, vendors, and other related organizations.

- The RU had adequate funding.
- The RU had a communications strategy that promoted unreserved sharing of information.
- The RU's mission, policies, and objectives were understood.

2.1.2 Observations and Conclusions

The team observed that the RU was staffed to complete its tasks and its structure was suitable for the current work scope leading into the construction phase, except for implementing the details of industrial hygiene and safety (IH&S) regulation (e.g., stop-work authority, granting of waivers, and inspection procedures), which was recently assigned to the RU and therefore was still being developed. The RU had the authority necessary to effectively fulfill the functions of an independent regulator (via DOE/RL-96-26, the Memorandum of Agreement [MOA]), with good buy-in from DOE-HQ. In addition, the team determined that the current organization provided clear lines of authority and program coordination and that the RU had established open communications on its activities, including a website in which reports were docketed. MDs and procedures were in place for the RU to do its job. The RU had adequate funding to complete its work, and appropriate management tools were in place to manage the work.

Based on these observations, the team concluded that the RU met the major elements of the evaluation criteria in the area of management and organization.

The following suggestions for improvements were made in the area of management and organization:

- While the RU's structure was adequate for the scope of work, RU management should assess the organizational structure as they move to the project's construction and operation phases (e.g., what the RU will look like three and five years from now). The RU should also define what its work scope will be after the Construction Authorization Request (CAR) is approved.
- While the RU must maintain its independence from ORP, more interactions in the areas of safety management and quality assurance would enhance the project. For example, the RU regulates BNFL and ORP regulates CH2M HILL Hanford Group, Inc. (CHG); however, BNFL and CHG will interface directly in certain safety areas. Therefore, the RU and ORP should coordinate the safety regulation between BNFL and CHG so the two contractors aren't given different direction in areas where they must interface. The RU also needs to be cognizant of the quality assurance requirements for the immobilized high-level waste as defined by the commercial waste repository program since BNFL must meet the quality assurance requirements of the commercial repository for the immobilized high-level waste.
- Another area for improvement deals with managing the RU staff. The team observed that some RU staff did not have a working knowledge of the specific areas of the MDs (e.g., handling proprietary information and resolving disputes). In addition, the RU staff should strive to become more technically knowledgeable of the BNFL advancing design

details. This improvement possibly could be accomplished by increasing the frequency of the RU internal technical training sessions as a way to gain a better understanding of the advancing design based on the results from inspections, design reviews, document reviews, and topical meetings. The frequency of the RU internal technical training sessions could be increased by requiring RU technical staff to provide instruction on a topic of their choosing on a rotating weekly basis.

- As the RU moves forward to the construction phase, it should determine which facilities it will authorize for construction (e.g., all facilities, only "safety-related" construction work, or all construction work) before limited construction is authorized. For example, will the RU authorize construction of roads, temporary facilities, and the BNFL administration building?

2.1.3 Recommendations

The team made the following recommendations in the area of management and organization:

1. The RU should confirm or redefine the organizational structure for the project's next phase. This effort should include such things as revisiting the RU's role in continued safety document reviews, defining the scope of the resident inspector program, defining how regulation of IH&S will be managed, and identifying additional capabilities that may be needed in the RU staff (e.g., electrical engineering, construction experience, chemical process operating experience, and general knowledge of IH&S).

2. While the RU must maintain its independence from ORP, the RU should engage in more interactions with ORP in areas such as IH&S, overlapping safety management (i.e., where BNFL and CHG will have to interact), and quality assurance as it relates to the requirements for the immobilized high-level waste going to the commercial repository.

3. The RU should determine which facilities it will authorize for construction.

2.2 Interfaces

2.2.1 Evaluation Criteria

The primary criteria for evaluating interfaces were as follows:

- The functional interfaces were established, understood, and implemented between the RO/RU and the RL Manager; the Assistant Secretary for Environmental Management (EM-1); the Assistant Secretary of Environment, Safety and Health (EH-1); the NRC; and other federal, state and nongovernmental organizations in areas of critical support.

- The RU had established and implemented functional programs that resolved differing professional opinions and responded to allegations/whistleblowers.

Subcriteria for evaluating interfaces were as follows:

- The RU effectively coordinated regulatory authorities (e.g., with RL, ORP, the Office of Environmental Management [EM] , and the Office of Environment, Safety and Health [EH]).

- The RU maintained liaisons with other governmental and nongovernmental organizations as appropriate (e.g., NRC, federal and state organizations, and advisory groups).

- The RU had defined its role for public information and involvement.

- The RU had processes for handling differing professional opinions and allegations.

2.2.2 Observation and Conclusions

The team found that interfaces between the RU and BNFL, the other RL offices, ORP, DOE-HQ offices, the NRC, the Defense Nuclear Facilities Safety Board (DNFSB), and the public were being implemented through the *Regulatory Plan* (RL/REG-97-10). The team observed that interfaces with BNFL in design reviews and inspections were very professional, and interfaces at topical meetings and in workshops had improved since the previous self-assessment. The team also observed that interfaces with NRC had been good in most areas and were meeting the terms of RL/REG-97-12, the Memorandum of Understanding (MOU) between NRC and the RU. The team observed that the proposed changes to the MOU between the RU and NRC may help NRC staff be more directly involved rather than remain totally independent of the RU. Interfaces with ORP were generally good, with the right level of information being exchanged. The biweekly meetings provided an excellent interchange between the RU and ORP. Interfaces with DOE/HQ EM and EH were positive, with good information exchange occurring at the Quarterly and Executive Review Board meetings. Interfaces with RL, while limited (e.g., training, emergency planning, fire protection, and employee concerns), were going well. The team determined that interfaces with DNFSB, while limited, also were going well. For example, the direct meetings between the RO and the DNFSB at DNFSB Headquarters were viewed as very positive. Finally, interfaces with the public (e.g., through the Hanford Advisory Board) had been open and professional.

Based on these observations, the team concluded that the RU satisfied the major elements of the evaluation criteria to facilitate critical interfaces.

The following suggestions for improvements were made in the area of interfaces:

- The RU should work closer with ORP to enhance the overall project, particularly in areas such as safety and quality assurance where the contractors (i.e., BNFL and CHG) will need to interface with one another. The RU and ORP should ensure that the two contractors don't get conflicting direction in areas where they must interface. (See Section 2.1.2.)

- As the RU moves toward regulating IH&S, it should communicate with the RL Analysis and Evaluation Division (AE&D) on how this area will be regulated and determine if the AE&D should play a role.

2.2.3 Recommendations

The team made the following recommendations in the area of interfaces:

1. As the RU moves toward regulating IH&S, it should determine what role the RL Analysis and Evaluation Division should play.

2.3 Staffing

2.3.1 Evaluation Criteria

The primary criteria for evaluating staffing were as follows:

- The RU's staffing size and experience supported completion of expected tasks.
- RU staff were qualified.
- RU staff demonstrated an understanding of the facilities being analyzed.
- RU staff were able to use and coordinate the work of support personnel including DOE, NRC, and contractors.

Subcriteria for evaluating staffing were as follows:

- The RU had a competent core staff possessing broad technical capabilities and mature judgment.
- The RU staff, including contractors, included personnel in the following functional areas, when appropriate: assessment and authorization, regulatory inspection and enforcement, development of regulations and guides, and administrative and legal support.
- The RU staff met appropriate qualifications.
- Training was available to the RU staff.
- The RU's fulltime staffing was adequate for performing assessments and monitoring consultant performance.
- The RU used DOE staff, NRC, and consultants, as necessary.

2.3.2 Observation and Conclusions

The team observed that the RU staff was highly educated, experienced, and trained; and their skills and experience matched well with the functional areas of regulation: assessment and authorization, regulatory inspection and enforcement, development of regulations and guides, and administration. RL provided legal support to the RU, if needed.
The team also observed that the RU had done an excellent job of recruiting experienced and trained staff to fulfill its mission. All appropriate RU employees had completed the DOE Technical Qualification Program. In addition, the team determined that the RU staff had the expertise to direct and monitor the work being performed by the support contractors. The current staffing, supplemented by support contractors, had the competence to manage and complete the current work scope, with the possible exception of IH&S, which was recently added to the RU's work scope. The RU had identified technical areas where additional support staff were needed (e.g., electrical engineering and heating, ventilation, and air conditioning) and was arranging for the necessary technical support to conduct upcoming document reviews. A procedure was in place for qualifying inspectors.

Based on these observations, the team concluded that the RU was meeting the evaluation criteria in the area of staffing.

The following suggestions for improvements were made in the area of staffing:

- The RU should re-evaluate its staffing needs as the project moves into construction. For example, the need for staff with experience to support areas such as electrical, instrument and control, construction, operations, and IH&S should be re-evaluated. (This was discussed previously in Sections 2.1.2 and 2.1.3.) In addition, management expectations should be defined and the training of current staff should be re-evaluated for the project's next phase. If needed, additional training should be identified and planned using individual performance plans and individual development plans according to RL procedures. Also, the need and training for additional lead inspectors should be re-assessed as well as the training needs for IH&S regulation.

- *Regulatory Unit Management Directives*, MD 1.5, "Organization and Operation of the Regulatory Unit," was out of date (i.e., it didn't reflect the recent organizational changes within RL or the creation of ORP) and should be updated after the revised Policy and MOA are approved.

2.3.3 Recommendations

The team made the following recommendations in the area of staffing:

1. The RU should re-assess its training needs as it moves to the project's next phase.

2. MD 1.5, "Organization and Operation of the Regulatory Unit," should be updated to reflect the new ORP and RL organizations.

2.4 Technical Standards and Requirements

2.4.1 Evaluation Criteria

The primary criteria for evaluating technical standards and requirements were as follows:

- The RU had a process to approve regulations, safety principles, and criteria that ensure the health and safety of workers, the public, and environment.
- The RU-approved standards for radiological, nuclear, and process safety were clear and consistent with regulations, principles, and criteria.
- The RU consistently interpreted and applied requirements.

Subcriteria for evaluating technical standards and requirements were as follows:

- The RU had prepared or adopted requirements and guides for the major stages of the project and the activities pertinent to each stage.
- The RU had formulated and stipulated a set of top-level standards and principles to the contractors as a basis for them to prepare subordinate standards.
- The RU had defined a process for the contractors to prepare subordinate standards.
- The RU had reviewed and approved the contractors' proposed set of subordinate standards.
- The RU provided a “backfit” process for implementing standards not included in the initial set.
- The RU had developed requirements and guides according to a plan and schedule, including a process for identifying needed standards and codes and guidance to the contractors for preparing submittals.

2.4.2 Observation and Conclusions

The team observed that the RU had a well-defined process in place and working to define the necessary regulations, safety principles, and criteria for radiological, nuclear, and process safety to ensure the health and safety of workers, the public, and the environment. The team also observed that the RU had approved standards for radiological, nuclear, and process safety that were clear and consistent with the regulations, principles, and criteria; and a mechanism was in place to modify the approved standards. However, the team found that the capability to monitor IH&S, which was recently assigned to the RU, was still being developed.

The team also observed that the RU effectively used its expertise to interpret and apply requirements to the Contractor. In addition, the team found that the RU top-level standards and principles applied to all stages of the project; the Contractor’s proposed set of subordinate

standards had been approved; and an Authorization Basis Amendment Request (ABAR) process was in place and was being implemented to make needed changes to the approved authorization basis. The Contractor had been given guidance for preparing documents and defining the mechanism for making changes to the approved standards and authorization basis. Finally, the team reviewed the backfit process for managing RU-initiated changes to the Contractor's authorization basis (e.g., newly emerging issues) and determined that the RU had successfully implemented the process.

Based on the observations, the team concluded that the elements of the evaluation criteria had been met in the area of technical standards and requirements.

The team had no suggestions for improvements in the area of technical standards and requirements.

2.4.3 Recommendations

The team had no recommendations in the area of technical standards and requirements.

2.5 Authorization Process

2.5.1 Evaluation Criteria

The primary criterion for evaluating the authorization process was as follows:

- The RU established and implemented an authorization process that controlled safety, provided authority at the necessary level, and considered major phases of the contracting process as well as continuous Contractor activities.

Subcriteria for evaluating the authorization process were as follows:

- The RU had the authority needed to fulfill its responsibilities.
- The RU granted authorization via official documents delineating the specific terms of approval.
- The RU could suspend or revoke operating authorization for cause and could enforce its will through appropriate legal means.
- After granting authorization of an activity, the RU could change the terms of that authorization if necessary.
- The RU conducted timely and appropriate planning in anticipation of authorization requests.

- The RU had an authorization process that encompassed the regulation of siting, design, construction, commissioning, and decommissioning and provided authorization and oversight appropriate to each of these stages.

- The RU had an authorization process that was ongoing from site planning through decommissioning.

2.5.2 Observation and Conclusions

The team observed that an authorization process was in place to regulate BNFL. The MOA granted the RU the authority and independence, consistent with the statutory obligations of DOE, to ensure the effective performance of its responsibilities and to regulate the radiological, nuclear, and process safety of activities for the project's current phases; and the authorization process was directly applicable to the future stages of the project. The team also observed that because the RU was recently assigned regulation of IH&S, approval of BNFL's IH&S process had not been completed. The RU should define how it will regulate IH&S, including such things as how it will interface with Region X of the Occupational Safety and Health Administration, how it will process requests for variances, and the type and frequency of inspections that will be done. In addition, the team found that Contractor activities were monitored on a continuous basis using the authorization process. A formal dispute resolution process for regulatory issues was in place for settling disputes between BNFL and the RU.

The team found conflicting information relative to the RU's authority to withdraw authorization once it had been granted. MD Handbook 5.3, "Corrective Action Program Implementation," states in Section G that the RO can withdraw authorization, in whole or in part, if the Contractor is unable or unwilling to provide adequate safety or otherwise fulfill its responsibilities related to radiological, nuclear, or process safety. However, Section 4.9 of DOE/RL-0003, *Regulatory Process for Radiological, Nuclear, and Process Safety for the TWRS Privatization Contractors*, states that the operating authorization may be revoked or suspended in whole or in part by the RO. Thus, DOE/RL-0003 appears to limit withdrawal of authorization to the operating authorization only and not to design or construction.

Finally, the team concluded that the RU had done a good job of planning for the necessary regulatory reviews of BNFL submittals, including planning for the authorization request for construction. A clearly defined process (i.e., ABAR process) was in place to make changes to the authorization basis. These changes could be made on a continuous basis.

Based on these observations, the team concluded that the RU was meeting the evaluation criteria for the authorization process.

The following suggestion for improvement was made in the area of authorization process:

- During the interviews, the team found that both BNFL and the RU agreed that the Integrated Safety Management Plan and the Quality Assurance Program and Implementation Plan need major changes before the CAR is submitted to make the documents more useful to both BNFL and the RU. Therefore, more flexibility may be necessary in making changes to these documents. The RU should review its process for

making and approving major changes to approved documents, particularly where wholesale changes are needed.

2.5.3 Recommendations

The team made the following recommendations in the area of authorization process:

1. Because the RU was recently assigned regulation of the IH&S area, the RU should clearly define how it will regulate industrial safety, including the process for resolving issues and findings related to the *Occupational Safety and Health Administration Act*.

2. The RU should revise Section G of MD Handbook 5.3 to clarify that authorization withdrawal applies to operating authorization.

3. The RU should review the process used for making and approving major changes to approved documents.

2.6 Document Reviews

2.6.1 Evaluation Criteria

The primary criteria for evaluating document reviews were as follows:

- The RU's review and assessment of safety documentation were comprehensive, accurate, and consistent.

- The RU's guidance was clear, useful, and timely and was implemented.

- The RU's review schedules were met to the extent that quality was not compromised.

Subcriteria for evaluating document reviews were as follows:

- The RU's safety reviews were based on submittals that were complete and accurate; engineering solutions were feasible and capable of meeting requirements; and safety requirements were clear.

- The RU had established format and content guides.

- The RU protected proprietary and other sensitive information submitted by the Contractor.

- The RU's review program was appropriate to the various stages of the authorization process.

- The RU established an appropriate schedule for submittals at an early date; best efforts were made to meet schedules, but the quality of reviews was not compromised.

2.6.2 Observation and Conclusions

The team observed that the RU had done an excellent job of providing timely and thorough guidance to BNFL on expectations for the required regulatory submittals. The guidance had been well received by BNFL and the documents were of high quality. The team also found that the RU had done a good job of planning for the forthcoming regulatory document reviews. Although the time period for the reviews was tight, it appeared that the reviews could be completed in the time allocated. The team determined that the RU had established schedules for reviewing the BNFL regulatory submittals well before the submittal date and had made plans for staffing the necessary reviews. The team also observed that the RU, with support from the technical support contractors, had the necessary staff to perform comprehensive and accurate reviews of the safety documentation.

The team found that the more recent reviews of BNFL regulatory documents, such as the *Design Safety Features* deliverable, had gone better than previous reviews because the RU had provided BNFL with clearer guidance on the RU's expectations for the reviews. The team observed that Contractor documents containing proprietary information were generally handled and stored according to MD 2.1, "Information Management," although based on interviews, the team found inconsistent knowledge of how proprietary information should be handled.

After reviewing an RU ABAR approval document, the team found that the RU's safety evaluation was very thorough and contained a detailed explanation of the impact of each proposed change.

Based on these observations, the team concluded that the RU was meeting the evaluation criteria for document reviews.

The following suggestions for improvements were made in the area of document reviews:

- The RU should reinforce the requirements for protecting proprietary information during the day-to-day use of the documents, perhaps by instituting more formality into the process. The RU also should clearly reiterate to BNFL what constitutes "proprietary information" before BNFL submits the CAR.

- Interviews with RU staff suggested that before major reviews were started, the RU review team leader should consider providing written examples of safety summaries for the reviewers to use in writing Safety Evaluation Reports (SERs).

- The RU should put a desk instruction in place outlining the document control process so that personnel other than the document control specialist can access documents in the specialist's absence.

2.6.3 Recommendations

The team made the following recommendations in the area of document reviews:

1. The RU should reinforce the requirements for protecting proprietary information during day-to-day document reviews. The RU should also clearly reiterate to BNFL what constitutes proprietary information.

2. The RU should put a desk instruction in place outlining the document control process.

3. Before the major reviews are started, the RU review team leader should consider providing written examples of safety summaries for the reviewers to use in writing SERs.

2.7 Inspection and Enforcement

2.7.1 Evaluation Criteria

The primary criteria for evaluating inspection and enforcement were as follows:

- The RU had established an inspection program, which included thorough reviews, direct inspection, or observations of the Contractor's work activities, to ensure compliance with limits and conditions specified in the authorization agreement and the Contract.

- The RU formally documented and understood enforcement authority and processes.

Subcriteria for evaluating inspection and enforcement were as follows:

- The RU conducted inspections and requested enforcement actions as necessary.

- The RU effectively planned the inspection program before each stage of the regulatory process.

- The RU received appropriate cooperation from the contractors on inspection and enforcement functions.

- The RU could perform inspections on short notice if needed.

- The RU had various means to enforce compliance, including corrective action processes.

- The RU had a legal framework for enforcement actions.

- The RU could suspend or revoke an operating authorization for cause.

- The RU could impose or recommend penalties.

2.7.2 Observation and Conclusions

Through interviews and observations, the team found that approved inspection procedures had been prepared for the design-phase-related inspections and had been sent to BNFL at least 60 days before any planned inspection. The inspection procedures were based on the approved

authorization basis for establishing inspection requirements, were available in advance, and were published on the RU website. The team also observed that the RU could perform inspections on short notice (i.e., unannounced inspections) if the RO approved them in advance.

The team also observed that the inspections had been performed in an open, well-disciplined, and professional manner following the protocols established by the RU. The RU completed 13 inspections of BNFL between November 1998 and April 2000, using 22 different inspectors. Interactions with BNFL on inspections had been good, with appropriate formality and communications. The team observed that the RU had a process in place to ensure that corrective actions from inspection reports proposed by the Contractor were reviewed and approved; the corrective actions were put in the commitment management system (CMS) report and were tracked to completion. The team observed that the RU could recommend enforcement on corrective actions up to and including recommendation of penalties (to be enforced by DOE's Office of Enforcement and Investigation [EH-10]) and withdrawal of operating authorization (see Section 2.5.2). The team also determined that the RU inspectors were trained for performing the inspections, including use of a qualification program for inspectors and lead inspectors. Finally, the team observed that changes to the authorization basis, for example, through ABARs, were not directly linked to the inspection procedures.

Based on these observations, the team concluded that the RU had established and implemented an inspection program that was responsive to the current phase of the project.

The following suggestions for improvements were made in the area of inspection and enforcement:

- The RU should review its schedule for future inspections and ensure that it has enough qualified lead inspectors available, particularly as the project transitions from design to construction when RU staff will need to provide both safety document design reviews and onsite inspections. While 22 different employees have been involved in the 13 inspections of BNFL, only 3 lead inspectors have been used.

- The RU should clearly define the scope of the resident inspector program before construction starts. A draft administration inspection procedure has been written but has not been finalized and approved by the RO. The resident inspection program should begin early in the construction phase.

- The RU should establish a formal program to ensure that as the authorization basis changes (e.g., by means of the ABAR process), the inspection procedures are brought up to date.

2.7.3 Recommendations

The team made the following recommendations in the area of inspection and enforcement:

1. The RU should review its schedule for future inspections and ensure that enough qualified lead inspectors are available. Additional inspectors and lead inspectors should be identified.

2. The RU should clearly define the scope of the resident inspector program before construction starts.

3. As the authorization basis changes, the RU should establish a formal program to ensure that inspection procedures are brought up to date.

2.8 Lessons Learned and Corrective Actions

2.8.1 Evaluation Criteria

The primary criteria for evaluating lessons learned and corrective actions were as follows:

- The RU had an effective lessons-learned program in place and was using it.
- The RU identified, assigned, and tracked corrective actions to completion.

Subcriteria for evaluating the lessons-learned and corrective actions area were as follows:

- The RU had implemented a lessons-learned system to ensure that changes, improvements, and enhancements derived from assessing the regulatory program were consistently applied.
- RU responses to assessments were accurate and appropriate in terms of schedule and content.
- The RU tracked to completion actions resulting from assessments and applied lessons learned.
- The RU's lessons-learned system was coordinated with the Hanford Sitewide Lessons-Learned program as defined in "Managing Lessons Learned" (HNF-PRO-067, formerly WHC-CM-1-5).
- The RU had implemented a Corrective Action Program that provided the project with a process to ensure that regulatory expectations resulting from the Contract and the regulatory process were met.
- The RU monitored the identification, implementation, and effectiveness of corrective actions taken by the Contractor.
- The RU's Corrective Action Program was linked to the DOE enforcement program and incorporated relevant DOE enforcement policy and guidelines.
- The RU's Corrective Action Program ensured that noncompliances with DOE nuclear safety requirements were referred to EH-10 for possible enforcement action.
- The Corrective Action Program ensured that failures to meet regulatory expectations were promptly identified and that appropriate corrective actions were taken.

- The RU maintained appropriate Corrective Action Program records.

2.8.2 Observation and Conclusions

The team observed that while the RU had a lessons-learned program as covered by MD 1.6, "Coordination of Regulatory Program Assessments and Lessons Learned," the program was being conducted informally. Lessons learned were being done for document reviews, such as the Standards Approval Package and the *Design Safety Features* deliverable but not with the rigor described in MD 1.6.

The team also determined that the RU had a Corrective Action Program for tracking corrective actions in the BNFL program as covered by MD 5.3, "Correction Action Program Implementation." The RU had implemented a corrective action system to track to completion corrective actions taken by BNFL to correct failures to meet regulatory expectations. The RU Corrective Action Program, as defined in MD 5.3, was linked to the DOE enforcement program and incorporated relevant DOE enforcement policy and guidelines. MD 5.3 also states that noncompliance with DOE nuclear safety requirements, if found, were to be referred to EH-10 for possible enforcement. The team found that failures to meet regulatory expectations, e.g., in inspections, were promptly identified and that appropriate corrective actions were identified and implemented. BNFL corrective actions were tracked to completion.

While the RU tracked corrective actions from BNFL, the team observed that no system was used for tracking improvement opportunities within the RU, such as the need to update the MDs. The RU should consider using MD 5.3 or create some other less formal tracking system for tracking internal RU corrective actions to completion.

Two suggestions for improvement were made in the area of lessons learned and corrective actions:

- The RU lessons-learned program primarily focused on the document review process. The RU should consider expanding the program to include areas such as the inspection program, design reviews, ABAR process, business practices, and document control. The RU lessons-learned program should be strengthened to ensure that changes, improvements, and enhancements derived from assessments were identified, assigned, and tracked to completion.

- While the RU's CMS tracked BNFL commitments for closure, the RU verification of closure should be more timely. For example, of 56 BNFL commitments entered in the CMS report during 1999, only 3 had been verified as closed by March 2000, even though many of the items were well beyond their completion date.

2.8.3 Recommendations

The team made the following recommendations in the area of lessons learned and corrective actions:

1. The RU's lessons-learned program should be expanded beyond document reviews and strengthened to ensure that improvements derived from assessments were identified, assigned, and tracked to completion.

2. The RU should assess the timeliness of closure of items in the CMS.

2.9 Integrated Safety Management

2.9.1 Evaluation Criteria

The primary criterion for evaluating ISM was as follows:

- The RU was applying ISM within the RU in conformance with the letters issued by the Secretary of Energy ("Safety-Accountability and Performance"[3]) and the Deputy Secretary of Energy ("Implementation of Integrated Safety Management"[4]).

Subcriteria for evaluating ISM were as follows:

- The RU had a plan to put ISM in place by September 2000, including the integration of any other safety initiatives and programs (such as the Voluntary Protection Program, Work Smart Standards, Enhanced Work Planning, and International Standards Organization Programs).

- RU management was implementing the elements of ISM as defined in DOE Policy 450.4, "Safety Management System Policy."

- The RU had established a process whereby action plans to correct deficiencies identified in independent evaluations of safety and emergency response were developed within 60 days after the oversight report was issued.

2.9.2 Observation and Conclusions

The team observed that the RU was fully implementing ISM with BNFL according to MD 5.7, "Assessment of Contractor's ISMP Implementation." The RU had approved an ISM program for BNFL and had conducted inspections against their program (e.g., on the standards selection process and on safety integration). BNFL's ISM program assigned line management responsibility for safety, clearly defined roles and responsibilities, and identified the safety standards and requirements. In a letter[5] from the Manager of RL to the ASEM, dated April 5, 2000, RL declared that an ISM system had been fully implemented for the TWRS-P Contractor.

[3] "Safety-Accountability and Performance," Memorandum to all Department and Contractor Employees from the Secretary of Energy, dated March 3, 1999.
[4] "Implementation of Integrated Safety Management," Letter from T.J. Glauthier, Deputy Secretary of Energy, dated October 25, 1999.
[5] 00-RU-0295, "Implementation of Integrated Safety Management System for the Tank Waste Remediation System Privatization [TWRS-P] Contractor") K.A. Klein, RL, to C.L. Huntoon, DOE, dated April 5, 2000.

Overall responsibility for implementing ISM according to the letters from the Secretary of Energy and Deputy Secretary of Energy is assigned to RL. The RU is expected to conform with the RL and DOE documentation applicable to federal staff. The team observed that the RU had a robust internal system of policies, plans, positions, and procedures as depicted in the latest revision of the RU document hierarchy. While not required, the RU should consider the potential benefits of putting a separate internal plan together on how it is implementing the guiding principles and core functions of ISM within the RU. ISM will become increasingly important as the RU staff do more work in the field (e.g., construction inspections) because they may be exposed to more potential hazards.

2.9.3 Recommendations

The team made the following recommendation in the area of ISM:

1. Although the RU is expected to conform with RL and DOE processes on ISM and the RU has a robust internal document hierarchy, the RU should consider the potential benefits of writing a specific internal plan on how it is implementing ISM within the RU.

2.10 Quality Assurance

2.10.1 Evaluation Criteria

The primary criterion for evaluating quality assurance was as follows:

- RL quality assurance requirements were being applied to the project, subject to the requirements of RL's *Quality Assurance Program Description* (QAPD).

Subcriteria for evaluating quality assurance were as follows:

- The RU's quality assurance program was being conducted under the authority of the RL Manager and was subject to the provisions of the Manager's QAPD.
- The RO was fully accountable for achieving quality in RU-assigned activities.
- The RU had applied quality provisions to accomplish the Implementing Activities identified in the *Regulatory Plan* (RL/REG-97-10).

2.10.2 Observation and Conclusions

The team observed that the RU quality assurance program was being conducted under the authority of the RL Manager and under the provisions of the RL QAPD. However, the team found that while elements of the RL quality assurance program were found throughout the RU (e.g., management assessments, records management, document control, and definition of roles and responsibilities), the RU had not established a formal documented process on how it met the

requirements of the RL QAPD. The team found that the RO was fully accountable for achieving quality within the RU.

2.10.3 Recommendations

The team made the following recommendation in the area of quality assurance:

1. The RU should consider documenting more formally how it meets the requirements of the RL QAPD.

2.11 Completion of Actions from a Previous Self-Assessment

As part of this self-assessment, the assessment team reviewed the RU's progress in completing the 13 recommendations from the 1998 self-assessment (shown in Table 1). As the table shows, the assessment team determined that all but one of the recommendations had been completed. The one recommendation remaining open was item 5 in Table 1, which recommended that Section 4.1.1 of RL/REG-97-06, *Regulatory Unit Management and Administrative Manual*, be changed to ensure that the MDs were included within the scope of new employee orientation. Revision 3 of RL/REG-97-06 contained no reference to the MDs. Therefore, the following recommendation was made:

1. RU management should revise RL/REG-97-06, Section 4.1.1, to include the MDs as part of the new employee orientation.

3.0 REFERENCES

36 CFR 1236, "Management of Records," *Code of Federal Regulations*, as amended.

Design Safety Features, RPT-W375-RU00001, Volumes I and II, Rev. 0, BNFL, Inc., 1999.

DOE-G-1324.5B, "Record Maintenance and Disposition," U.S. Department of Energy, 1996.

DOE P 450.4, "Safety Management System Policy," U.S. Department of Energy, 1996.

DOE/RL-96-0003, *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

DOE/RL-96-25, *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1996.

DOE/RL-96-26, *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1996.

Integrated Safety Management Plan, BNFL-5193-ISP-01, Rev. 4, BNFL Inc., 1998.

"Managing Lessons Learned," HNF-PRO-067, Fluor Hanford, 1998.

Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 673) Public Law 91-596, as promulgated in 29 CFR 1900, et. Seq.

Quality Assurance Program and Implementation Plan, BNFL-5193-QAP-01, Rev. 4, BNFL Inc., 1998.

Quality Assurance Program Description (QAPD), Rev. 0, U.S. Department of Energy, Richland Operations Office, January 1992.

RL/REG-97-04, *Openness Policy and Plan*, Rev. 4, U.S. Department of Energy, Richland Operations Office, 1999.

RL/REG-97-05, *Regulatory Unit Management Directives*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

MD 1.3, Rev. 3, "Planning, Budgeting, and Reporting"
MD 1.5, Rev. 1, "Organization and Operation of the Regulatory Unit"
MD 1.6, Rev. 3, "Coordination of Regulatory Program Assessments and Lessons Learned"
MD 2.1, Rev. 2, "Information Management"
MD 5.3, Rev. 0, "Corrective Action Program Implementation"
MD 5.7, Rev. 0, "Assessment of Contractor's ISMP Implementation."

RL/REG-97-06, *Regulatory Unit Management and Administrative Manual*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

RL/REG-97-10, *Regulatory Plan*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

RL/REG-97-12, *Memorandum of Understanding Between the Nuclear Regulatory Commission and the Department of Energy – Cooperation and Support for Demonstration Phase (Phase I) of DOE Hanford Tank Waste Remediation System Privatization Activities*, C. Paperiello and J. D. Wagoner, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1997.

4.0 LIST OF TERMS

AE&D	Analysis and Evaluation Division
ABAR	Authorization Basis Amendment Request
ASEH	Assistant Secretary for Environment, Safety and Health
ASEM	Assistant Secretary of Environmental Management
BNFL	BNFL Inc.
CAR	Construction Authorization Request
CHG	CH2M HILL Hanford Group, Inc.
CMS	commitment management system

DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
EH	DOE's Office of Environment, Safety and Health
EH-10	DOE's Office of Enforcement and Investigations

Table 1. Status on Closeout of Recommendations from 1998

Recommendation from 1998 Audit	RU Point of Contact	Comment
1. RU management should continue to place priority on conducting a retreat. The retreat should involve as many federal employees and support services contractor personnel as possible. An agenda should be developed before hand and the services of an external facilitator should be obtained.	D.C. Gibbs	1. After the RU reorganized in May 1998, an offsite retreat was held for all RU federal staff in June 1998 using two outside facilitators. A second offsite retreat was held in September 1999. **(Completed)**
2. After the retreat, the RU should follow through on its intention to formalize a more realistic organization. It should then revise position descriptions.	D.C. Gibbs	2. After the RU was reorganized in May 1998, position descriptions were updated to reflect the new organization. **(Completed)**
3. The RU should continue its efforts to complete staffing. However, it should not compromise unnecessarily on the skills and qualifications of personnel it selects. Priority should be placed on filling the position of Openness Coordinator.	D.C. Gibbs	3. The RU became fully staffed in January 1999. There was no compromise on skill and qualifications. An Openness Coordinator was designated. **(Completed)**
4. The Lead Regulatory Process Administrator should re-evaluate the content of the monthly performance reports. If necessary, the governing Management Directive (Handbook 1.3, Part IV, Section B) should be revised to include only meaningful information.	R.J. Light	4. The format of the monthly was changed and Handbook MD 1.3, "Information, Budgeting, and Reporting," was changed to remove some content requirements. The monthly report now follows the new MD 1.3 format. **(Completed)**
5. RU team leaders should assure that new employees receive the required "systematic and thorough orientation" on regulatory processes. Section 4.1.1 of the RL/REG-97-06 should be changed to ensure that the Management Directives are included within the scope of the orientation.	L.F. Miller, Jr. R.C. Barr P.P. Carier	5. This had not been done. Section 4.1.1 of RL/REG-97-06, Rev. 3, did not mention the MDs. It listed DOE/RL-96-25, DOE/RL-96-26, and the four regulatory documents (DOE/RL-96-0003, -0004, -0005, and –0006). **(Incomplete)**
6. RU management should follow-through on its stated intention to revise and upgrade the *Openness Plan* (RL/REG-97-04).	A.R. Hawkins	6. The *Openness Policy and Plan* was revised in September 1997 and had been revised three times since then. The last revision was in November 1999. **(Completed)**
7. RU management should ensure that the lessons-learned process is followed. It should also ensure that it is formally enhanced as experience with the process is accumulated.	R.C. Barr	7. The RU lessons-learned program was being conducted informally. Lessons learned were being done for document reviews, such as the Standards Approval Package and the *Design Safety Features* deliverable; however, it was not being done with the rigor described in MD 1.6, "Coordination of Regulatory Program Assessments and Lessons Learned." **(Partially Completed)**

8. The Lead Regulatory Process Administrator should, with the advice of the team leaders, re-evaluate the format of the contractor commitment tracking database (Handbook 2.2, Part II, Section B). The database should be reconfigured to optimize its usefulness.	R.J. Light	8. The Data Management Systems handbook (MD Handbook 2.2) was revised in August 1998. The database administrator linked the Inspection Finding System to the commitment tracking system. Fields were updated to capture pertinent commitment information. **(Completed)**
9. Team leaders should re-evaluate the methods they are using to ensure that Contractor commitments are properly and completely entered in the commitment tracking with the database. The re-evaluation should include people who had been entering this information to ensure that their experience and insight are used.	L.F. Miller, Jr. R.C. Barr P.P. Carier	9. The RU had a CMS in place to track formal (i.e., written) commitments from BNFL. Review of the CMS reports showed that the primary entries were related to the RU-conducted inspection reports. BNFL commitments were being properly entered into the system and were being tracked to completion. However, RU verification of completion should be more timely. **(Completed)**
10. The Lead Regulatory Process Administrator should re-evaluate the process used to identify RU commitments to external organizations. The identification process should be enhanced to ensure that commitments are systematically identified and entered into the system.	R.J. Light	10. The Information Management Handbook (Handbook 2.1) was revised in February 1999 (Rev. 4) to include an Action Tracking Sheet for RU actions. The Information Management Coordinator is responsible for overseeing management of the Action Tracking Sheet to ensure that RU response and actions were completed as scheduled. **(Completed)**
11. The Lead Regulatory Process Administrator should ensure that adequate resources are applied to the record management and associated administrative functions. Resources should be adequate to ensure that no risk will occur if the record management specialist is permitted to take a normal two-week vacation.	R.J. Light	11. Records management and associated information management system responsibilities were shared among the information management system staff to ensure continuity of job functions and to provide multiple access to the database. **(Completed)**
12. The Lead Regulatory Process Administrator should take action to ensure that records are properly protected from damage. Credit may be taken for records scanned and stored on the network. Other records, including in-process records, should be protected from fire and actuation of the fire protection sprinkler system.	R.J. Light	12. Electronic copies of RU documents and correspondence were maintained in the Records Management Information System and external file server. A fire-proof file cabinet was used for storing proprietary information received from the Contractor. **(Completed)**
13. The Lead Regulatory Process Administrator should identify any RU vital records as defined by 36 CFR 1236, "Management of Records," and DOE-G-1324.5B, "Record Management Program." The administrator should take action to ensure that the required policies, plans, and procedures are in place to protect and reconstruct vital records. If necessary, the requirements of Handbook 2.1 should be revised to specify a more appropriate RU process for managing vital records.	R.J. Light	13. A description of "vital records" (i.e., emergency operating records and rights and interest records) was added to Part III, Section G.3 of Rev. 4 of the Information Management Handbook (Handbook 2.1) in February 1999. Protection and reproduction of records were discussed in Handbook 2.1. **(Completed)**

EM	DOE's Office of Environmental Management
HQ	Headquarters
IH&S	industrial hygiene and safety
ISM	integrated safety management
MD	Management Directive
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NRC	U.S. Nuclear Regulatory Commission
ORP	Office of River Protection (U.S. Department of Energy)
QAPD	Quality Assurance Program Description
RL	Richland Operations Office
RO	Regulatory Official
RU	Regulatory Unit
SER	Safety Evaluation Report
TWRS-P	Tank Waste Remediation System Privatization

This page intentionally left blank.

Appendix A. Subject Areas and Primary Criteria for the 2000 Self-Assessment

Subject Area	Assessment Criteria
1. Management and Organization	• The Regulatory Unit (RU) organization was structured and staffed in a manner to complete its tasks within schedule, while ensuring safety. • The RU's authorities and responsibilities were clearly understood and discharged. • The RU's organizational practices provided a sound safety culture.
2. Interfaces	• The functional interfaces were established, understood, and implemented between the Regulatory Official (RO)/RU and the U.S. Department of Energy's (DOE's) Richland Operations Manager; the Assistant Secretary for Environmental Management; the Assistant Secretary of Environment, Safety and Health; the U.S. Nuclear Regulatory Commission (NRC); and other federal, state and nongovernmental organizations in areas of critical support. • The RU had established and implemented functional programs that resolved differing professional opinions and responded to allegations/whistleblowers.
3. Staffing	• The RU's staffing size and experience supported completion of expected tasks. • RU staff were qualified. • RU staff demonstrated an understanding of the facilities being analyzed. • RU staff were able to use and coordinate the work of support personnel including DOE, NRC, and contractors.
4. Technical Standards and Requirements	• The RU had a process to approve regulations, safety principles, and criteria that ensure the health and safety of workers, the public, and environment. • The RU-approved standards for radiological, nuclear, and process safety were clear and consistent with regulations, principles, and criteria. • The RU consistently interpreted and applied requirements.
5. Authorization Process	• The RU established and implemented an authorization process that controlled safety, provided authority at the necessary level, and considered major phases of the contracting process as well as continuous Contractor activities.
6. Document Reviews	• The RU's review and assessment of safety documentation were comprehensive, accurate, and consistent. • The RU's guidance was clear, useful, and timely and was implemented. • The RU's review schedules were met to the extent that quality was not compromised.
7. Inspection and Enforcement	• The RU had established an inspection program, which included thorough reviews, direct inspection, or observations of the Contractor's work activities, to ensure compliance with limits and conditions specified in the authorization agreement and the Contract. • The RU formally documented and understood enforcement authority and processes.

Subject Area	Assessment Criteria
8. Lessons Learned and Corrective Actions	• The RU had an effective lessons-learned program in place and was using it. • The RU identified, assigned, and tracked corrective actions to completion.
9. Integrated Safety Management	• The RU was applying integrated safety management within the RU in conformance with the letters issued by the Secretary of Energy ("Safety-Accountability and Performance") and the Deputy Secretary of Energy ("Implementation of Integrated Safety Management").[6]
10. Quality Assurance	• RL quality assurance requirements were being applied to the project, subject to the requirements of RL's *Quality Assurance Program Description.*

[6] "Safety-Accountability and Performance," Memorandum to all Department and Contractor Employees from the Secretary of Energy, dated March 3, 1999; and "Implementation of Integrated Safety Management," Letter from T.J. Glauthier, Deputy Secretary of Energy, dated October 25, 1999.

Appendix B. Staff Interviewed for the Regulatory Unit's 2000 Self-Assessment

Interviewee	Organization
Adams, Jim	Regulatory Unit
Barr, Rob	Regulatory Unit
Carier, Pat	Regulatory Unit
Chen, Ko	Regulatory Unit
Gibbs, Clark	Regulatory Unit
Gilbert, Rob	Regulatory Unit
Griffith, Bob	Regulatory Unit
Hawkins, Al	Regulatory Unit
Hopkins, Dianne	Regulatory Unit
Hunemuller, Neal	Regulatory Unit
Kalman, George	Regulatory Unit
Kaushal, Ninu	Regulatory Unit
Light, Ron	Regulatory Unit
Liu, Chung-King	Regulatory Unit
McCormick-Barger, Jim	Regulatory Unit
Miller, Lewis, Jr.	Regulatory Unit
Polehn, Jeanie	Regulatory Unit
Pasciak, Walt	Nuclear Regulatory Commission
Tokar, Mike	Nuclear Regulatory Commission
Bell, Gerry	DOE-RL
Wright, Allison	DOE-RL
Lightner, Ralph	DOE/HQ – EM (by phone)
Thompson, Owen	DOE/HQ – EM (by phone)
Brown, Neil	Office of River Protection
Taylor, Bill	Office of River Protection
Dobson, Alan	BNFL Inc.
Edwards, Don	BNFL Inc.
Klein, Dennis	BNFL Inc.
Burks, Lisa	Support Contractor
Hansen, Ann	Support Contractor
Smoter, Bob	Support Contractor

This page left intentionally blank.

Appendix C. Documents Reviewed for the Self-Evaluation

This appendix lists the Regulatory Unit (RU) documents that were reviewed for the 2000 self-assessment and then shows which documents were reviewed for each subject area (Table 2).

1. DOE/RL-96-25, *Policy for Radiological, Nuclear, and Process Safety Regulations of TWRS Privatization Contractors*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1996.

2. DOE/RL-96-26, *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors*, U.S. Department of Energy, Richland Operations Office, Rev. 0, 1996, and Rev. 1 (draft), 1998.

3. IR-00-001, *Design Process Inspection Report*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 2000.

4. IR-99-001, *Personnel Training and Qualification Inspection Report*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

5. IR-99-005, *Configuration Management Program Inspection Report*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

6. IR-99-008, *Safety Integration Inspection Report*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

7. Letter 00-RU-0020, D.C. Gibbs, Regulatory Unit, to M.J. Lawrence, BNFL Inc., "Safety Evaluation by the DOE RU of Proposed ABAR Rev. 0, NPH Analysis and Design Approach," dated October 27, 1999.

8. Letter 00-RU-0036, D.C. Gibbs, Regulatory Unit, to M.J. Lawrence, BNFL Inc., "Approval of Authorization Basis Amendment Request, Miscellaneous Revisions to SRD," dated October 27, 1999.

9. Letter 00-RU-0086, A.J. Dobson, BNFL Inc., to D.C. Gibbs, Regulatory Unit, "SRD Revisions for ABAR-W375-00004 and ABAR-W375-99-00008," dated November 10, 1999.

10. Letter 99-RU-0147, "Regulatory Unit Evaluation of BNFL Inc.'s Safety Requirements Document (SRD) Rev 2B, Sections 5.3 and 5.4," M.J. Bullock, BNFL Inc., from D.C. Gibbs, Regulatory Unit, dated February 9, 1999.

11. Letter 99-RU-0338, "Safety Evaluation by the DOE RU of Proposed ABAR to the ISMP for the RPP-P," M.J. Lawrence, BNFL Inc., from D.C. Gibbs," Regulatory Unit, dated June 10, 1999.

12. *Quality Assurance Program Description (QAPD)*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1992.

13. RL Policy Directive 340.1, *Resolution of Differing Professional Views and Opinions Policy and Procedure*, U.S. Department of Energy, Richland Operations Office, 1998.

14. RL-96-01, *Quality Assurance Program Description*, Rev. B, U.S. Department of Energy, Richland Operations Office, 2000.

15. RL/REG-00-01, *Regulatory Unit Evaluation of the BNFL Radiation Protection Program for Design*, Rev. 2, U.S. Department of Energy, Richland Operations Office, 2000.

16. RL/REG-97-04, *Openness Policy and Plan*, Rev. 4, U.S. Department of Energy, Richland Operations Office, 1999.

17. RL/REG-97-05, *Regulatory Unit Management Directives*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.
    a. MD 1.1, Rev. 2, "Implementation of Regulatory Principles and Achievement of Policy Objectives"
    b. MD 1.2, Rev. 1, "Regulatory Unit Management Directive System"
    c. MD 1.4, Rev. 3, "Conduct of Meetings with External Parties"
    d. MD 1.5, Rev. 1, "Organization and Operation of the Regulatory Unit"
    e. MD 1.6, Rev. 3, "Coordination of Regulatory Program Assessments and Lessons Learned"
    f. MD 2.3, Rev. 0, "Commitment Management System"
    g. MD 5.3, Rev. 0, "Corrective Action Program Implementation"
    h. MD 5.7, Rev. 0, "Assessment of Contractor's ISMP Implementation"
    i. Handbook 1.6, Rev. 3, "Coordination of Regulatory Program Assessments and Lessons Learned"
    j. Handbook 2.3, Rev. 0, "Commitment Management System"
    k. Handbook 5.3, Rev. 0, "Corrective Action Program Implementation"
    l. Handbook 5.7, Rev. 0, "Assessment of Contractor's ISMP Implementation."

18. RL/REG-97-06, *Regulatory Unit Management and Administrative Manual*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

19. RL/Reg-97-10, *Regulatory Plan*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

20. RL/REG-97-12, *Memorandum of Understanding Between the Nuclear Regulatory Commission and the Department of Energy – Cooperation and Support for Demonstration Phase (Phase I) of DOE Hanford Tank Waste Remediation System Privatization Activities*, C. Paperiello and J. D. Wagoner, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1997.

21. RL/REG-97-13, *Regulatory Unit Position on Contractor-Initiated Changes to the Authorization Basis*, Rev. 5, U.S. Department of Energy, Richland Operations Office, 1999.

22. RL/REG-98-06, *Corrective Action Program Description*, Rev. 3, U.S. Department of Energy, Richland Operations Office, 1999.

23. RL/REG-98-07, *Regulatory Unit Policy for Training and Training Plan*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1999.

24. RL/REG-98-08, *Regulatory Unit Position on Selected Hazards Control Strategy Issue*, Rev. 2, U.S. Department of Energy, Richland Operations Office, 1998.

25. RL/REG-98-14, *Regulatory Unit Position on New Safety Information and Back-fits*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

26. RL/REG-98-16, *Regulatory Unit Interface Plan*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 2000.

27. RL/REG-98-17, *Regulatory Unit Position on Tailoring for Safety*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

28. RL/REG-98-18, *Regulatory Unit Position on Radiological Safety for Hanford Co-located Workers*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1998.

29. RL/REG-98-21, *Regulatory Unit Position on Implementing and Assuring Compliance with Integrated Safety Management*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1998.

30. RL/REG-98-24, *Inspection Program Implementation Plan for the Regulatory Unit Oversight of the TWRS-P Contractors*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 2000.

31. RL/REG-98-25, *Inspection Administrative Procedures*
    a. A-101, Rev. 0, "Inspection Planning and Scheduling"
    b. A-102, Rev. 0, "Announced and Unannounced Inspections and Related Information Requests"
    c. A-103, Rev. 0, "Entrance and Exit Meetings"
    d. A-106, Rev. 0, "Verification of Corrective Actions"

32. RL/REG-98-26, *Inspection Technical Procedure*, U.S. Department of Energy, Richland Operations Office.
    a. I-101, Rev. 0, "Quality Assurance Assessment"
    b. I-102, Rev. 0, "Configuration Management Assessment"
    c. I-106, Rev. 0, "Personnel Training and Qualification Assessment"
    d. I-109, Rev. 0, "Safety Integration Assessment"
    e. ITP-1-113, Draft, "Structural Concrete Inspection"
    f. ITP-1-114, Draft, "Structural Steel Inspection"
    g. ITP-1-131, Draft, "Document Control and Records Management Program Inspection."

33. RL/REG-99-05, *Review Guidance for the Construction Authorization Request*, Rev. 2, U.S. Department of Energy, Richland Operations Office, 1999.

34. RL/REG-99-07, *Design Review Guides*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1999.

35. RL/REG-99-08, *Planning Handbook for BNFL Inc. Design Safety Features Submittal Review*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1999.

36. RL/REG-99-09, *Regulatory Unit Position on the Tank Waste Remediation System Privatization Waste Treatment (WTP) Regulatory Basis (Including Authorization Agreements)*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

37. RL/REG-99-11, *Regulatory Unit Position on Regulation of BNFL's Industrial Hygiene and Safety Program*, Rev. 2, U.S. Department of Energy, Richland Operations Office, 2000.

38. RL/REG-99-16, *Regulatory Unit Position on the Selection of Design Standards*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

39. RL/REG-99-17, *Review Guidance for the TWRS-P Limited Construction Authorization Request*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 2000.

40. RL/REG-99-18, *Regulatory Unit Position on Assessment of the Contractors' Integrated Safety Management Program as Described in the Integrated Safety Management Plan*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1999.

41. RL/REG-2000-05, *DOE Regulatory Unit Evaluation Report on BNFL's QAPIP*, Rev. 2, U.S. Department of Energy, Richland Operations Office, 2000.

42. "Safety-Accountability and Performance," Memorandum to all Department and Contractor Employees from the Secretary of Energy, dated March 3, 1999.

Table 2. Documents Reviewed by Subject Area

Subject Area	Documents Reviewed
1. Management and Organization	1, 2, 17a, 17b, 17d, 18, 19
2. Interfaces	2, 13, 16, 17c, 17d, 20, 26
3. Staffing	17d, 23
4. Technical Standards and Requirements	7-11, 17a, 17e-g, 21, 24, 25, 27-29, 35-38, 40
5. Authorization Process	1, 7-11, 13, 17a, 17d, 19, 21, 24, 25, 27-29, 35-38, 40
6. Document Reviews	7-11, 15, 19, 33-35, 39, 41
7. Inspection and Enforcement	3-6, 22, 30, 31a-d, 32a-g
8. Lessons Learned and Corrective Actions	17 e-j, 22, 30
9. Integrated Safety Management	17a, 17d, 17h, 17l, 21, 42
10. Quality Assurance	12, 14, 19

Appendix D. Recommendations from the 2000 Self-Assessment of the Regulatory Unit (RU)

Recommended Activity	Timing	Assignee
1. The Regulatory Unit (RU) should confirm or redefine the organizational structure for the project's next phase. This effort should include such things as revisiting the RU's role in continued safety document reviews, defining the scope of the resident inspector program, defining how regulation of industrial health and safety (IH&S) will be managed, and identifying additional capabilities that may be needed in the RU staff (e.g., electrical engineering, construction experience, chemical process operating experience, and general knowledge of IH&S).	Prior to Construction Authorization	D.C. Gibbs
2. While the RU must maintain its independence from the Office of River Protection (ORP), the RU should engage in more interactions with ORP in areas such as IH&S, overlapping safety management (i.e., where BNFL and CH2M HILL Hanford Group [CHG] will have to interact) and quality assurance as it relates to the requirements for the immobilized high-level waste going to the commercial repository.	Prior to Construction Authorization	D.C. Gibbs
3. The RU should determine which facilities it will authorize for construction.	Prior to Construction Authorization	D.C. Gibbs
4. As the RU moves toward regulating IH&S, it should determine what role the Richland Operations Office's (RL's) Analysis and Evaluation Division should play.	Prior to Construction Authorization	A.R. Hawkins
5. The RU should re-assess its training needs as it moves to the project's next phase.	Prior to Construction Authorization	N.K. Hunemuller
6. Management Directive (MD) 1.5, "Organization and Operation of the Regulatory Unit," should be updated to reflect the new ORP and U.S. Department of Energy (DOE)/RL organizations.	Prior to Execution of Phase 1B-2 but after the revised Policy and MOA are approved	R.J. Light
7. Because the RU was recently assigned regulation of the IH&S area, the RU should clearly define how it will regulate industrial safety, including the process for resolving issues and findings related to the *Occupational Safety and Health Administration Act*.	Prior to Construction Authorization	A.R. Hawkins
8. The RU should revise Section G of MD Handbook 5.3, "Corrective Action Program Implementation," to clarify that authorization withdrawal applies to operating authorization.	Prior to Limited Construction Authorization	P.P. Carier
9. The RU should review the process used for making and approving major changes to approved documents.	Prior to Construction	L.F. Miller, Jr.
10. The RU should reinforce the requirements for protecting proprietary information during day-to-day document reviews. The RU should also clearly reiterate to BNFL what constitutes proprietary information.	Prior to Limited Construction Authorization	R.C. Barr
11. The RU should put a desk instruction in place outlining the document control process.	Prior to Limited Construction	R.J. Light
12. Before the major reviews are started, the RU review team leader should consider providing written examples of safety summaries for the reviewers to use in writing Safety Evaluation Reports.	Prior to Execution of Phase 1B-2	L.F. Miller, Jr.

Recommended Activity	Timing	Assignee
13. The RU should review its schedule for future inspections and ensure that enough qualified lead inspectors are available. Additional inspectors and lead inspectors should be identified.	Prior to Construction Authorization	P.P. Carier
14. The RU should clearly define the scope of the resident inspector program before construction starts.	Prior to Construction Authorization	P.P. Carier
15. As the authorization basis changes, the RU should establish a formal program to ensure that inspection procedures are brought up to date.	Prior to Execution of Phase 1B-2	P.P. Carier
16. The RU's lessons-learned program should be expanded beyond document reviews and strengthened to ensure that improvements derived from assessments were identified, assigned, and tracked to completion.	Prior to Construction Authorization	R.C. Barr
17. The RU should assess the timeliness of closure of items in the Commitment Management System.	Prior to Limited Construction Authorization	P.P. Carier
18. Although the RU is expected to conform with RL and DOE processes on integrated safety management (ISM) and the RU has a robust internal document hierarchy, the RU should consider the potential benefits of writing a specific internal plan on how it is implementing ISM within the RU.	Prior to September 2000	P.P. Carrier
19. The RU should consider documenting more formally how it meets the requirements of the RL *Quality Assurance Program Description*.	Prior to Limited Construction Authorization	A.R. Hawkins
20. RU management should revise RL/REG-97-06, Section 4.1.1, to include the MDs as part of the new employee orientation.	Prior to Execution of Phase 1B-2	R.J. Light